UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK & CO., INC. and MSD TECHNOLOGY, L.P.,	:	
Plaintiffs,	:	**OPINION**
- against -	:	05 Civ. 3650 (DC)
	:	05 Civ. 3696 (DC)
MEDIPLAN HEALTH CONSULTING, INC., d/b/a/ RXNORTH.COM,	:	05 Civ. 3698 (DC) 05 Civ. 3699 (DC) 05 Civ. 3700 (DC)
Defendant.	:	05 Civ. 3701 (DC)
AND RELATED CASES.	:	

APPEARANCES: (See last page)

CHIN, D.J.

In these six related cases, defendants operate Canadian online pharmacies through which they offer U.S. consumers generic versions of plaintiffs' popular cholesterol medication, Zocor. Plaintiffs filed complaints against defendants for patent infringement, trademark infringement, and unfair competition under federal and state law. Defendants move for partial summary judgment pursuant to Fed. R. Civ. P. 56(c) on the issue of patent remedies. They contend that plaintiffs may only recover damages accrued from April 2005, when the suits were filed, to December 2005, when the patent expired, and may not obtain injunctive relief now that the patent has expired. Plaintiffs move for a continuance pursuant to Fed. R. Civ. P. 56(f) to allow them further discovery to determine which patent claims they plan to assert.

For the reasons set forth below, defendants' motion is granted in part and denied in part, and plaintiffs' motion is denied.

BACKGROUND

A. Facts

The parties and the facts relating to the trademark and unfair competition claims are described in the Court's ruling of March 30, 2006, on defendants' numerous motions to dismiss. See Merck & Co. v. MediPlan Health Consulting, Inc., 425 F. Supp. 2d 402 (S.D.N.Y. 2006). Accordingly, I now set forth only those undisputed facts relevant to the current motions.[1]

Merck & Co. ("Merck") is a pharmaceutical company that develops, manufactures, and markets prescription drugs. On April 24, 1984, U.S. Patent No. 4,444,784 (the "'784 patent") for "Antihypercholesterolemic Compounds" was issued to Merck and thereafter assigned to MSD Technology L.P. ("MSD"). (Compl. ¶¶ 3, 11 & Ex. A).[2] The commercial embodiment of the '784 patent is Zocor, a popular medication that reduces cholesterol and fatty substances in the blood. (Compl. ¶¶ 13, 15). Zocor pills are not marked with any indication that they are protected by a patent. Simvastatin is the active ingredient in Zocor. (Compl.

[1] Although defendants have not submitted a Local Rule 56.1 statement, there are no material facts in dispute, so I decline to deny the motion on this ground.

[2] "Compl." refers to the complaint in No. 05 Civ. 7000 against defendant MedCenter Canada Inc. The patent counts in all six cases are similar, and all other complaints will be referred to by the specific defendant charged.

¶ 13). Since November 1986, Merck has been the exclusive entity legally authorized by patent laws and the U.S. Food and Drug Administration (the "FDA") to sell simvastatin in the United States. (Compl. ¶¶ 14-15).

The '784 patent contains eighteen claims: twelve for compounds and compositions that inhibit the biosynthesis of cholesterol and six for methods of treating high cholesterol through administration of the covered compounds and compositions. (Compl. Ex. A. ('784 patent, at col. 26-27)). In compliance with federal law, plaintiffs listed the '784 patent in the FDA Orange Book, a publication of approved medications and their patent protection. The '784 patent expired on December 23, 2005.

Defendants are operators of Canadian online pharmacies that offer U.S. consumers generic simvastatin, among other products, through their websites.[3] The FDA has not approved defendants' sale of simvastatin in the United States.

B. Prior Proceedings

Plaintiffs filed the first action, No. 05 Civ. 3650, on April 8, 2005, and the remaining actions on April 11, 2005. The

[3] Defendants are: Mediplan Health Consulting, Inc. ("RxNorth"), which operates www.rxnorth.com (RxNorth Compl. ¶¶ 4, 5); North Pharmacy Inc. and PPI Pivotal Partners, Inc. (together, "CanadaPharmacy"), which operate www.canadapharmacy.com (CanadaPharmacy Compl. ¶¶ 4, 5); Universal Drug Store Ltd. ("Universal"), which operates www.universaldrugstore.com (Universal Compl. ¶¶ 4, 5); Canada Drugs.com("CanadaDrugs"), which operates www.canadadrugs.com (CanadaDrugs Compl. ¶¶ 4, 5); Medcenter Canada ("MedCenter"), which operates www.medcentercanada.com (Compl. ¶¶ 4, 5); and Total Care Pharmacy Ltd.(d/b/a "CrossBorder"), which operates www.crossborderpharmacy.com (CrossBorder Compl. ¶¶ 4, 5).

first count of each complaint alleges infringement of the '784 patent. The remaining counts relate to plaintiffs' trademark and unfair competition claims. Defendants moved to dismiss those claims, and on March 30, 2006, this Court granted the motions in part and denied them in part.

Defendants filed the instant joint motion for partial summary judgment on November 2, 2005. Plaintiffs filed their opposition and motion for continuance on November 23, 2005.

DISCUSSION

Defendants move to preclude damages or injunctive relief based on (1) plaintiffs' failure to provide patent protection notice under the patent marking statute, 35 U.S.C. § 287(a), prior to filing suit in April 2005, and (2) the expiration of the '784 patent on December 23, 2005. Plaintiffs oppose, contending that additional discovery is necessary under Rule 56(f). I first discuss defendants' motion. Then I discuss plaintiffs' motion.

A. Defendants' Motion

1. Pre-Suit Damages

Section 287(a), which is commonly known as "the marking statute," provides in pertinent part:

> Patentees . . . may give notice to the public . . . either by fixing [on the patented article] the word 'patent' or the abbreviation 'pat.', together with the number of the patent, or . . . by fixing to it, or to the package . . . a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the

> patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for the infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

35 U.S.C. § 287(a). Hence, where a patented article has not been marked with the patent number, the patentee cannot recover damages absent notice to the alleged infringer. See Gart v. Logitech, Inc., 254 F.3d 1334, 1345 (Fed. Cir. 2001). The purpose of the notice requirement is to ensure that the alleged infringer knew of the adverse patent and his infringing conduct before being held liable. See id. (citations omitted).

Defendants' motion to bar plaintiffs' recovery of pre-suit damages turns on the following legal issues: first, whether the marking statute applies to a patent that contains both method and product claims, and second, whether registration of the '784 patent in the FDA Orange Book constitutes statutory notice of the infringement. I address each in turn.

a. Applicability of the Marking Statute

Where the patent is only for a method or process, the marking statute does not apply because no physical item exists to be marked. See Am. Med. Sys., Inc. v. Med. Eng'g Corp., 6 F.3d 1523, 1538 (Fed Cir. 1993). Thus, notice of infringement is not required for a patent that solely contains method claims. See State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1073 (Fed. Cir. 2003) ("[T]he notice requirement . . . does

not apply where the patent is directed to a process or method.") (citations and quotations omitted); Am. Bank Note Holographics, Inc. v. Upper Deck Co., No. 92 Civ. 9146 (JGK), 1997 WL 30886, at *2 (S.D.N.Y. Jan. 27, 1997) (same) (citations omitted). The '784 patent, however, covers both methods (for treating high cholesterol) and products (the actual compositions administered in treatment, embodied by the simvastatin compound, Zocor). Plaintiffs contend that where, as here, a patent contains both method and product claims, compliance with the statute is not required if only the method claims of the patent are asserted. Defendants, on the other hand, maintain that plaintiffs cannot avoid their duty to mark or otherwise provide notice simply by electing to assert only method claims. I agree that marking is required where the patent contains both method and product claims.

The Federal Circuit and other courts have so held. In American Medical Systems, Inc. v. Medical Engineering Corp., 6 F.3d 1523 (Fed Cir. 1993), the Federal Circuit considered whether the marking statute applied to a patent that contained both method and apparatus claims. See id. at 1527 (noting that the patent "claims an apparatus and method for packaging a fluid-containing penile prosthesis"). In holding that plaintiff had a duty to mark the products, the court stated:

> Where the patent contains both apparatus and method claims . . . to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so if it intends to

> avail itself of the constructive notice provisions of section 287(a).

Id. at 1538-39. Hence, where a combined patent covers a tangible article, plaintiffs are not relieved of the duty to mark simply by asserting only the method claims of the patent. See Halliburton Servs. v. Smith Int'l Inc., 317 F. Supp. 2d 719, 725 (E.D. Tex. 2004) (relying on Am. Med. Sys. to require marking where plaintiff "distributed tangible items created by the [patent] methods and by which [it] could have given notice"); Philips Elecs. N. Am. Corp. v. Contec Corp., 312 F. Supp. 2d 649, 651-52 (D. Del. 2004) (same); Honeywell Int'l Inc. v. Hamilton Sundstrand Corp., No. Civ. A. 99-309 (GMS), 2001 WL 66345, at *4 (D. Del. Jan. 4, 2001) (same); Mosel Vitelic Corp. v. Micron Tech., Inc., No. Civ. A. 98-449 (GMS), 2000 WL 1728351, at *1 (D. Del. Feb. 25, 2000) (finding "immaterial" the distinction between asserting only method claims and asserting both method and apparatus claims).

Because plaintiffs produced a physical item (the Zocor pills) on which they could have given notice of protection of their patented methods for treating high cholesterol, compliance with section 287(a) was required. See Devices for Med., Inc. v. Boehl, 822 F.2d 1062, 1066 (Fed. Cir. 1987) ("The claimed method is the use of the product. Having sold the product unmarked, [the patentee] could hardly maintain entitlement to damages for its use by a purchaser uninformed that such use would violate [the] method patent.").

Plaintiffs argue that marking tangible items in a combined method and product patent is only required where infringement of both the method and the product claims has been asserted. For support, they rely on an earlier Federal Circuit decision, Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1076 (Fed. Cir. 1983), language in the American Medical Systems decision, and an unreported decision from the Northern District of Georgia, Coca-Cola Co. v. Pepsico, Inc., No. 02 Civ. 2887 (RWS) (N.D. Ga. Sept. 29, 2004).

In Hanson, the court did not impose a notice requirement where only the method claims of a combined method and product patent had been infringed. 718 F.2d at 1083 (applying rule that "the notice requirement . . . does not apply where the patent is directed to a process"). The Hanson court clearly sought, however, to limit its reach to the particular facts of that case. See id. at 1083 ("Our decision is a narrow one. We hold only that on the record in this case, the findings of the magistrate are not clearly erroneous."). The court's brief analysis turned largely on the specific procedural history, including both the lower court's and the appellate court's description of the patent-in-suit (for generating artificial snow) as a process patent, despite the presence of apparatus claims. See id. at 1082-83 (noting that the appellate court "stated in the first sentence of its opinion that 'the patent

alleged to be infringed is [for] a process for making snow for winter sports'" (alterations in original) (citations omitted)).[4]

Plaintiffs also look to language in American Medical Systems, noting a "distinction" between cases, like Hanson, that allege infringement of "only method claims" and those that allege infringement of "both the apparatus and method claims of the same patent." Am. Med. Sys., 6 F.3d at 1538. Before concluding that plaintiffs were required to mark their products, the court noted that "both apparatus and method claims of the . . . patent were asserted and there was a physical device produced by the claimed method that was capable of being marked." Id. at 1539. Thus, according to plaintiffs, the marking statute only applies where a tangible item exists for marking and a patentee alleges infringement of both the product and method claims of the same patent.

Such a limited interpretation of American Medical Systems, however, would be at odds with the very purposes of the marking statute: to avoid innocent infringement, encourage patentees to give public notice of patent protection, and aid the public in identifying patented articles. See Nike, Inc. v. Wal-Mart Stores, Inc., 138 F.3d 1437, 1443 (Fed. Cir. 1998) (citations omitted). The interpretation plaintiffs urge the Court to adopt would undermine these aims by allowing plaintiffs

[4] The Sixth Circuit had decided the appeal in the liability phase of the case because the Federal Circuit did not yet exist. See Hanson v. Alpine Valley Ski Area, Inc., 611 F.2d 156 (6th Cir. 1979).

to circumvent the marking requirement through artful pleading. Only one district court has adopted this reasoning, and given the weight of the contrary authority, I disagree with its conclusion. See Coca-Cola Co. v. Pepsico, Inc., No. 02 Civ. 2887 (RWS), slip op. at 4 (N.D. Ga. Sept. 29, 2004) (concluding that "because only the method claims of the '421 Patent are asserted . . . § 287(a) is inapplicable vis-a-vis that patent and accused device"). But see, e.g., Halliburton, 317 F. Supp. 2d at 725 (holding plaintiff has duty to mark where tangible item exists by which notice of patented method could be given); Philips Elecs., 312 F. Supp. 2d at 651-52 (same).

Accordingly, plaintiffs were required to comply with section 287(a) regardless of whether they assert only the method claims of the '784 patent.[5]

b. Notice Under the Marking Statute

Notice under the marking statute "requires the affirmative communication of a specific charge of infringement by a specific accused product." Amsted Indus. Inc. v. Buckeye Steel

[5] Moreover, in view of the broad allegations of patent infringement in the complaint, arguably plaintiffs have already asserted both product and method claims of the '784 patent: "Defendants' sales and/or offers for sale of simvastatin products in New York and elsewhere in the United States, are without license or permission from Plaintiffs, and infringe the '784 patent under 35 U.S.C. § 271." (Compl. ¶ 29). Clearly, when they filed suit, plaintiffs wanted to preserve the option of proceeding on both the method and product claims. As a policy matter, patentees should be encouraged to mark their products, and permitting patentees to later on elect to proceed only on method claims to excuse non-compliance with the marking statute would undermine that goal.

Castings Co., 24 F.3d 178, 187 (Fed. Cir. 1994) (emphasis added); see also SRI Int'l, Inc. v. Advanced Tech. Labs., Inc., 127 F.3d 1462, 1470 (Fed. Cir. 1997) (holding the communication must convey, "with sufficient specificity," the patent holder's belief "that the recipient of the notice may be an infringer"). General statements to the industry about the patent's existence, absent a specific accusation of infringement, simply do not meet this standard. See AT & T Corp. v. Microsoft Corp., 290 F. Supp. 2d 409, 416-17 (S.D.N.Y. 2003) (relying, inter alia, on Amsted, 24 F.3d at 186-87).

Compliance with the marking statute is a question of fact upon which the patent holder bears the burden of persuasion. Loral Fairchild Corp. v. Victor Co. of Japan, Ltd., 906 F. Supp. 813, 816 (E.D.N.Y. 1995); see also Devices for Med., Inc. v. Boehl, 822 F.2d 1062, 1066 (Fed. Cir. 1987) (upholding denial of motion for new trial where plaintiff "failed to carry its burden of convincing the jury that it had performed affirmative acts in compliance with § 287"). The focus must be on what steps the patentee has taken to inform the defendants of their infringement, in light of all relevant communication between the parties. See Amsted, 24 F.3d at 187 (finding courts "must focus on the action of the patentee, not the knowledge or understanding of the infringer"); Eastman Kodak Co. v. Agfa-Gevaert N.V., No. 02 Civ. 6564, 2004 WL 1529226, at *4 (W.D.N.Y. July 2, 2004) (considering "the entirety of the relevant communications between the patentee and the alleged infringer" to determine whether

adequate notice given) (citations omitted). In this analysis, defendants' knowledge of the patent or of its infringement is "irrelevant." Amsted, 24 F.3d at 187.

Here, it is undisputed that plaintiffs failed to "mark" their Zocor product as called for by section 287(a). Thus, the damages period commenced when plaintiffs gave defendants actual notice of their infringement. While the filing of the complaints in April 2001 constituted notice for this purpose, plaintiffs contend that they provided defendants notice long before the complaints were filed by listing the '784 patent in the FDA Orange Book (officially titled "Approved Drug Products with Therapeutic Equivalence Evaluations"). The question appears to be one of first impression, as neither side has cited any case law considering the issue of whether an Orange Book listing constitutes notice under section 287(a). I conclude that it does not and, thus, summary judgment will be granted in favor of defendants on this issue.

The Orange Book came into existence as a result of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), which was enacted by Congress to balance the "competing policy interests" of "inducing pioneering research and development of new drugs and . . . enabling competitors to bring low-cost generic copies of those drugs to market." Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1327 (Fed. Cir. 2005). The law required plaintiffs to notify the FDA of the '784 patent for

listing in the Orange Book. See id. at 1328. The Orange Book provides "a streamlined mechanism for identifying . . . patent issues related to . . . proposed generic products" and "facilitat[ing] judicial resolution of the question whether the generic drug would infringe a pertinent patent." Apotex, Inc. v. Thompson, 347 F.3d 1335, 1338-39 (Fed. Cir. 2003).

In the Orange Book, the '784 patent is listed five times for various dosages under the product name "SIMVASTATIN; ZOCOR." The patent expiration date, December 23, 2005, is listed in the same row as the patent number.[6] This listing does not reference defendants or their products, nor was it sent directly to defendants. While the Orange Book is available to the public, notice under the law requires a specific charge of infringement by a specific accused product. The Orange Book is merely a catalog that informs the public of the patent's existence. Accordingly, it is just the kind of generalized warning to the industry that the courts have routinely found do not provide sufficient notice. See Lemelson v. Fisher Price Corp., 545 F. Supp. 973, 976 (S.D.N.Y. 1982) ("General knowledge in the marketplace of the existence of a patent is not a substitute for action by the patentee; to hold otherwise, in effect, would

[6] The 2006 Annual Edition of the Orange Book is available at http://www.fda.gov/cder/ob/docs/preface/eclink.htm, and defendants provide a reproduction in their Reply Memo, at 4. The Orange Book is published annually in printed and online versions. The entries for "Simvastatin; Zocor" are substantially similar in the years from 2003 to 2006. Neither party disputes that the expiration date in this action is December 23, 2005.

relieve a patentee of compliance with the requirements of section 287.").

The Orange Book, plaintiffs contend, is not just a generalized warning. Rather, it purportedly gives "direct and specific notice to an audience that is required by statute to seek out and heed that notice." (Pl. Opp. Mem. at 7). But the publication fails to provide direct notice where, as here, plaintiffs did not send the alleged infringers a copy. By arguing that defendants were required to consult the Orange Book under the relevant statutory scheme and that had they done so they would have received notice, plaintiffs urge the Court to focus on defendants' actions instead of their own. The burden of complying with the notice requirement, however, falls upon plaintiff.

Moreover, the Orange Book is over 1,000 pages long and the entries appear in an addendum listing hundreds of medications entitled "Prescription and OTC Drug Product Patent and Exclusivity List." A single listing buried in a thousand-plus page document is not the equivalent of a specific allegation of infringement against defendants, operators of pharmacies that distribute numerous prescription drugs. In addition, the fact that the Orange Book is published by a third party, the FDA, instead of the patentees themselves further supports a conclusion that the listing does not satisfy section 287(a). See AT & T, 290 F. Supp. 2d at 418 (finding an informational report delivered

to defendants from a party other than the patentee did not constitute statutory notice of infringement).

Finally, plaintiffs reach for a policy justification by focusing on defendants' knowledge of the '784 patent's existence. They argue that defendants should not be rewarded for violating the statutory scheme enacted by Congress. Eliminating pre-suit damages, plaintiffs contend, would thwart the important policy goals of the Hatch-Waxman Act by enabling their competitors to benefit from the pioneering research behind the '784 patent while flouting the requirements of the statutory scheme. Such policy questions, however, are beyond the appropriate inquiry of this Court for the law is clear in this area: defendants' knowledge of the patent's existence is simply irrelevant to the notice determination. See Amsted, 24 F.3d at 187. The inquiry "must focus on the action of the patentee, not the knowledge or understanding of the infringer." Id. Under that inquiry, plaintiffs failed to affirmatively communicate to defendants specific allegations of infringement by specific products before filing suit. Even if defendants were aware that their actions infringed Merck's patent, this knowledge still is not "proof that the infringer was notified of the infringement." 35 U.S.C. § 287; see Devices for Med., 822 F.2d at 1066.

Because the mere listing of the '784 patent in the Orange Book could not, as a matter of law, provide defendants with adequate notice, summary judgment is granted to defendants with respect to pre-suit damages. To the extent that plaintiffs

are able to prove infringement of the '784 patent, their damages will be calculated from the dates on which the suits were filed.

2. Post-Expiration Remedies

Defendants also move to preclude plaintiffs' recovery of damages and injunctive relief following the expiration of the '784 patent on December 23, 2005. The Court cannot award damages or injunctive relief based on defendants' infringement for the period after a patent's expiration because an expired patent cannot be infringed. See Lans v. Digital Equip. Corp., 252 F.3d 1320, 1328 (Fed. Cir. 2001) (finding plaintiff not entitled to damages or injunctive relief after expiration of patent).

Plaintiffs, however, may be entitled to damages based on the theory of "accelerated market entry" ("AME") or "accelerated reentry." See generally John M. Skenyon et al., Patent Damages Law and Practice § 2:69 (2006). Under this theory, plaintiffs seek compensation for lost sales after the patent's expiration based on defendants' entry into "the market at a level accelerated by its earlier infringement." BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 687 F. Supp. 134, 138 (S.D.N.Y. 1988); see also THK Am., Inc. v. NSK Ltd., 917 F. Supp. 563, 575 (N.D. Ill. 1996) (describing AME damages theory as "well recognized by the courts"); Amsted Indus. Inc. v. Nat'l Castings, Inc., 16 U.S.P.Q.2d 1737, 1754 (N.D. Ill. 1990) (permitting pursuit of AME damages based on post-expiration sales that defendants would not have made absent their pre-expiration infringement). While it is unclear whether plaintiffs will

ultimately prevail on the question of AME damages, they are entitled to try to prove what their post-patent expiration sales of Zocor would have been but for defendants' head start in the market due to their infringing conduct prior to December 23, 2005. (See Sims 11/22/05 Decl. ¶ 16). Moreover, defendants do not contest plaintiffs' right to seek AME damages at this time. (See Def. Reply Br. at 12).

Accordingly, defendants' motion for partial summary judgment is granted only with respect to any claims for injunctive relief and damages resulting from purported infringement following patent expiration. Defendants' motion is denied with respect to damages based on an AME theory.

B. Plaintiffs' Motion

In opposing defendants' motion for partial summary judgment, plaintiffs move for a continuance pursuant to Fed. R. Civ. P. 56(f) on the basis that further discovery is necessary. Plaintiffs' motion is denied because the discovery they seek is irrelevant to resolution of defendants' motion. See Contemporary Mission, Inc. v. N.Y. Times Co., 842 F.2d 612, 622 (2d Cir. 1988) (upholding denial of Rule 56(f) relief where discovery appears irrelevant to issues to be decided).

Plaintiffs seek a continuance to obtain purportedly essential discovery that will aid them in determining whether to elect to assert only the method claims of the '784 patent. For the reasons set forth above, such an election would make no difference to the outcome because, as a matter of law, plaintiffs

cannot avoid their duty to mark the Zocor products simply by asserting only the method claims of the '784 patent. Thus, a continuance is unnecessary, for there is no genuine issue of material fact left to be decided. See Gurary v. Winehouse, 190 F.3d 37, 43 (2d Cir. 1999) (noting that party moving pursuant to Rule 56(f) must show how facts sought "are reasonably expected to create a genuine issue of material fact") (citations and quotations omitted).

CONCLUSION

For the foregoing reasons, defendants' motion for partial summary judgment is granted in part and denied in part. Defendants' motion is granted with respect to pre-suit damages and damages emanating from defendants' conduct after the expiration of the '784 patent. Defendants' motion is denied with respect to plaintiffs' claims for AME damages. Plaintiffs' Rule 56(f) motion is denied.

SO ORDERED.

Dated: New York, New York
June 14, 2006

DENNY CHIN
United States District Judge

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